



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2001-DT-03

November 22, 2000

Michael T. Sunday, M.D.
Medical Director of Radiology
Community Memorial Hospital
748 S. Main
Cheboygan, MI 49721

Dear Dr. Sunday:

We are writing you because on November 14, 2000, your facility was inspected by a representative of the State of Michigan acting in behalf of the Food & Drug Administration (FDA). The inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following Level 1 finding at your facility:

1. Phantom quality control images were missing for a total of ~~4~~ weeks. The Quality Standards require that Phantom images be obtained at least weekly and documented to show results of the image evaluation.

The specific problem noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which was issued at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to placing your facility

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under a Directed Plan of Correction, charging your facility for the cost of onsite monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 finding that is listed on the inspection report provided to you at the close of the inspection. The Level 2 finding is:

1. There was no documentation of corrective action, prior to further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- the specific steps you have taken to correct the Level 1 and 2 violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).


Please submit your response to: Mr. David M. Kaszubski
Director Compliance Branch
U. S. Food & Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207-3179

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, you should consider the more stringent State requirements, if any. You should also send a copy to the State of Michigan radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and any additional State requirements in your response.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter only pertains to findings of your inspection and does not necessarily address other obligations you have under law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography>.

If you have more specific questions about mammography facility requirements or about the content of this letter, please feel free to contact Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,


for Raymond V. Mlecko
District Director
Detroit District

Enclosures: a/s